Exactech®

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K000242

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FEB 16

Exactech® AcuMatch™ Integrated Hip System
A-Series Corundum Acetabular Component

Special 510(k)
Summary of Safety and Effectiveness

Sponsor: Exactech® Inc.
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FDA Establishment Number 1038671

Contact: Gary J. Miller, Ph.D.
V.P. of Research and Development

Date: January 25, 2000

K000342

Exactech® AcuMatch™ Integrated Hip System
A-Series Corundum Acetabular Component

Special 510(k)
Summary of Safety and Effectiveness

Trade Name: Exactech® AcuMatch A-Series Corundum Acetabular Component

Common Name: Total Hip Prosthesis Acetabular Component

Classification Name: Prothesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented (Acetabular Component)

and

Prothesis, Hip, Semi-Constrained, Metal/Polymer, Cemented (Acetabular Component)

Legally Marketed Devices for Substantial Equivalence Comparison:

Model	Manufacturer	510(k) # (Product Codes)
AcuMatch A-Series Porous Coated	Exactech	993082 (LPH / JDI)
PSL	Osteonics	----------
Secur-Fit-HA	Osteonics	----------

Description:

The A-Series Corundum Cup consists of two acetabular shell options, cluster and multi-hole, with 14 available sizes for each option. There are only two basic shell designs but the addition of hydroxyapatite (HA) coating to each design creates a total of four options.

All shells are made from Ti-6Al-4V and have a corundum roughened surface finish. The shells are designed such that an interference condition is created between the prepared acetabulum and the rim diameter of the corundum surface of the shell. The shell designs allow for additional fixation by the use of Ti-6Al-4V bone screws which have been cleared for marketing under 510(k) # 993082 (Exactech AcuMatch A-Series

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Porous Coated Acetabular Component). A-Series Corundum Cups are intended for press-fit applications but components without the HA coating may also be used in cemented applications.

An ultra-high molecular weight polyethyelene (UHMWPE) liner assembles into the internal diameter of the shell. There are five primary liner designs with various sizes having the ability to accept 22, 26, 28, and 32 mm diameter femoral heads. The polyethyelene liner components have been previously cleared for marketing under 510(k) # 993082 (Exactech AcuMatch A-Series Porous Coated Acetabular Component).

Packaging and Sterilization:

AcuMatch A-Series Corundum Acetabular components are double packed in thermoformed trays and sealed with Tyvek® lids. The UHMWPE liners are vacuum sealed in two pouches. Inner packaging units are placed in cardboard containers and sealed with shrink wrap. The A-Series packaging also includes various product identification labels, sterility labels, product tracing labels and sterility indicators. The packaged product is sterilized by gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6}.

Intended Use:

AcuMatch A-Series Corundum Acetabular Components are indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, congenital hip dysplasia, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present and to restore mobility resulting from previous fusion.

AcuMatch A-Series Corundum Acetabular Components are indicated for press-fit applications. Components without the hydroxyapatite (HA) coating may also be used with bone cement.

Contraindications:

AcuMatch A-Series Corundum Acetabular Components are contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age, or activity level would cause the surgeon to expect early failure of the system.

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Substantial Equivalence Information:

The Exactech AcuMatch A-Series Porous (ref. 510(k) #K993082) and A-Series Corundum Acetabular Components have the same indications for use and contraindications for use. They also have similar technological features. The primary difference between the Exactech A-Series Corundum and Porous Components is the external finish and wall thickness of the two devices. The Corundum design resulted from design modifications to the A-Series Porous-Coated Acetabular Cup. The titanium beads were removed from the surface and corresponding area was replaced by a thicker cup wall. The outer surface was then roughened to achieve a "corundum" finish. The internal dimensions, liner options and shell-liner locking mechanisms are identical.

In addition to similarities to the A-Series Porous Cups, the A-Series Corundum has a similar geometry, material composition and surface characterization to other legally marketed acetabular shells. These include but are not limited to Osteonic's "Omnifit PSL" and "Secur-Fit-HA" designs. Each predicate device, like the Exactech A-Series Corundum Cup, is indicated for press-fit applications and supplied sterile. Each device also has enhanced surface properties and a coating of hydroxyapatite (HA).

Design Validation:

The primary difference between the Exactech A-Series Corundum Component and A-Series Porous Coated component (ref. 510(k) #K993082) is the external finish and wall thickness of the two devices. Because the wall thickness of the Corundum design is greater than the equivalent size Porous cup and the internal geometry of the two designs is identical, the performance data contained in the AcuMatch A-Series Porous Coated Acetabular Component submission (ref. #K993082) was considered sufficient to validate the new design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2000

Ms. Lisa Simpson
Regulatory Representative
Exactech
2320 NW 66th Court
Gainesville, Florida 32653

Re: K000242
Trade Name: Acumatch A-Series Corundum Acetabular Component and
Acumatch A-Series Corundum Acetabular Component with Hydroxyapatite
Regulatory Class: II
Product Codes: MEH and JDI
Dated: January 26, 2000
Received: January 27, 2000

Dear Ms.Simpson:

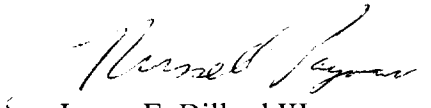
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® AcuMatch™ Integrated Hip System
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Indications for Use

510(k) Number: K000242

Device Name: Exactech® AcuMatch™ Integrated Hip System
A-Series Corundum Acetabular Component

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Seymour
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000242

Prescription Use X or Over the Counter Use _____